

REMARKS

The April 9, 2003 Official Action has been carefully reviewed. In light of the amendments presented herewith and the following remarks, favorable reconsideration and allowance of the application are respectfully requested.

Claims 1-3 are pending in the application. Claims 2-3 have been withdrawn from consideration. Claim 1 is currently under consideration.

Support for the present amendment to claim 1 can be found at page 6, lines 13-29 of the specification.

At the outset, the Examiner notes that the terminal disclaimer filed on December 11, 2002 was sufficient to overcome the double patenting rejection.

The Examiner then rejects claim 1 under 35 U.S.C. §112 first paragraph for alleged inadequate enablement.

The Examiner also rejects claim 1 under 35 U.S.C. §112 second paragraph for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The foregoing constitutes the entirety of the rejections raised in the April 9, 2003 Official Action.

In light of the present claim amendments and the following remarks, each of the above-noted rejections under 35 U.S.C. § 112, first and second paragraph, is respectfully traversed.

CLAIM 1 IS FULLY COMPLIANT WITH THE REQUIREMENTS OF 35 U.S.C.

§112 FIRST PARAGRAPH

Regarding the rejection of claim 1 under 35 U.S.C. §112 first paragraph for alleged inadequate enablement, it is the Examiner's position that the specification, while enabling for the cytochrome P450 inducers disclosed at pages 6-7 of the specification, is not enabling for any other agents which may be cytochrome P450 inducers.

The standards for enablement are set forth in MPEP § 2164,

The information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention. Detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention.

In § 2164.01, the MPEP continues,

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.

(Quoting *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988).

Applicants respectfully submit that the information in the disclosure is sufficient to make and use the claimed invention without undue experimentation.

Cytochrome P450 is described at page 6 of the

specification to be a group of enzymes which are an important component in the hepatic mixed function enzymatic system. The structural nature and specific activity (metabolism of drugs and chemicals) of cytochrome P450 is also described in the specification, and is well known in the art. Further, enzymatic inducers are well known in the art to refer to any compound which induces or activates an enzyme.

Therefore determining whether a compound or composition is a cytochrome P450 inducer is a relatively simple process, and would not require undue experimentation.

Nonetheless, solely in the interest of expedited prosecution, and without acquiescing to the Examiner's rejection, applicants have amended claim 1 to recite specific cytochrome inducers for which the present specification is conceded to be enabling at page 2 of the April 9, 2003 Official Action.

CLAIM 1 IS FULLY COMPLIANT WITH THE REQUIREMENTS OF 35 U.S.C.

§112 SECOND PARAGRAPH

With regard to the rejection of claim 1 under 35 U.S.C. §112 second paragraph, the Examiner states that it is unclear if the claimed composition comprises a plant extract containing a flavonoid and a cytochrome P450 inducer, or if the flavonoid is the cytochrome P450 inducer.

The claim as originally drafted recites specific components, including a flavonoid, and a cytochrome P450 inducer. These components are not listed in the alternative: each is a

specific feature of the claimed invention. Therefore, applicants respectfully submit that this recitation is clearly drawn to a flavonoid in addition to a cytochrome P450 inducer.

Nonetheless, solely in the interest of expediting prosecution, and without acquiescing to the Examiner's rejection, applicants have amended claim 1 to further clarify that the composition includes a flavonoid, in addition to a cytochrome P450 inducer.

CONCLUSION

In view of the amendments and remarks presented herein, it is respectfully urged that the rejections set forth in the April 9, 2003 Official Action be withdrawn and that this application be passed to issue. In the event the Examiner is not persuaded as to the allowability of claim 1, and it appears that any outstanding issues may be resolved through a telephone interview, the Examiner is requested to telephone the undersigned attorney at the phone number given below.

DANN DORFMAN HERRELL and
SKILLMAN, P.C.

Attorneys for Applicant

By Patrick J. Hagan
Patrick J. Hagan
Registration No. 27,643

PJH:jel